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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,302	10/16/2006	Jeremy Fairbank	UDL-121US	3386

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EXAMINER	
PATTON, AMANDA K	

ART UNIT	PAPER NUMBER
3709	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,302	FAIRBANK ET AL.	
	Examiner	Art Unit	
	Amanda Patton	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *15 February 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the limitation ""permitting switching between modes". There is insufficient antecedent basis for this limitation in the claim, as claim 7 only claims one mode and claim 9 states there are a plurality (more than one) of modes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10-11, 14-16, and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mann et al. (US Pat. 6,393,325, hereafter referred to as Mann).

Regarding **claim 1**, Mann teaches an apparatus for stimulation of the human body comprising:

- an array of stimulator elements (electrodes 24 as shown in Figure 5B) arranged to be operated in a plurality of stimulator activation zone configurations (electrodes

24, being used in a variety of electrode groups 45 as shown in Figures 6A and 6B and Col. 14 @ 45-50);

- a user interface device permitting the user to relate interface zones of the interface device to activation zones of the array of stimulator elements (programming system 10 including display screen 16, directional control device 12, and keyboard 14 as shown in Figure 2 and Col. 11 @ 45-60).

Regarding **claim 2**, Mann additionally teaches an apparatus wherein the interface device (programming system 10) permits spatial correlation between the zones of the interface device (the zones shown in the pain drawing of Figure 12 shown on display 16) and the active zones of the activation zones (electrode groups 45) of the array of stimulator elements (electrodes 24).

Regarding **claim 3**, Mann additionally teaches an apparatus wherein the interface device (programming system 10) includes an interface zone array (the pain drawing of Figure 12 shown on display 16) corresponding to the positional spacing of activation zones (electrode groups 45) of the array of stimulator elements (electrodes 24).

Regarding **claim 4**, Mann additionally teaches an interface device (display 16) includes a screen providing output relating to the activation zones of the array of stimulator elements.

Regarding **claim 5**, Mann additionally teaches an apparatus is operable in a mode in which user input to the interface device determines the activation zone configuration of the array of stimulator elements (Col. 28 @ 50-60).

Regarding **claim 6**, Mann additionally teaches an interface device that includes an input zone array (the pain drawing of Figure 12 shown on display 16) corresponding spatially to the activation zone configuration of the array of stimulator elements.

Regarding **claim 10**, Mann additionally teaches an apparatus including a means for storing results data (memory circuit 54 as shown in Figure 2 and Col. 11 @ 55-62).

Regarding **claim 11**, Mann additionally teaches an apparatus wherein the array of stimulator elements (electrodes 24) are carried in a predetermined spatial relationship on a support member (electrode arrays 23, 23' and 23" of Figures 6A, 6B, and 6C).

Regarding **claim 14**, Mann additionally teaches an apparatus wherein the support member (electrode array 23") comprises an implant for insertion in the body (connected to pulse generator 20' as shown in Figure 6C, and Title).

Regarding **claim 15**, Mann additionally teaches an apparatus wherein the support member (electrode array 23" of Figure 6C) includes space in between the electrodes, which can be considered barrier zones, in order to maximize attenuation beyond the locality of the stimulator elements.

Regarding **claim 16**, Mann additionally teaches an apparatus wherein the stimulator (electrodes) elements are arranged grid-wise in rows and columns (Col. 15 @ 10-20 and Figure 5B).

Regarding **claims 18 and 19**, Mann additionally teaches an apparatus wherein the stimulation intensity (pulse amplitude) and the activation duration (pulse width) of the stimulator elements can be varied (Col. 16 @ 65 – Col. 17 @ 5).

Regarding **claim 20**, Mann additionally teaches an apparatus including a control arrangement (stimulator processor 52) to control the interaction between the interface device (programming system 10) and the stimulator element array (array 23, all as shown in Figure 2).

Regarding **claim 21 and 22**, Mann additionally teaches an apparatus that includes data transmitting means (coil 28 of the programming device and coil 62 of the implantable stimulator) whereby results from the apparatus can be downloaded to a processor (stimulator processor 52) by a wireless connection, wherein the processor is part of the programming system 10 in one embodiment as shown in Figure 1A is a laptop.

Claims 1, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Sieracki et al. (US Pat. 6,308,102, hereafter referred to as Sieracki).

Regarding **claim 1**, Sieracki teaches an apparatus for stimulation of the human body, comprising:

- an array of stimulator elements (array of electrodes 33) arranged to be operated in a plurality of stimulator activation zone configurations (Col. 9 @ 30-50);
- a user interface device (patient interactive system 24, including display 30 and stylus 31) permitting the user to relate interface zones of the interface device to activation zones of the array of stimulator elements (Col. 8, @ 15-40).

Regarding **claims 7 and 8**, Sieracki additionally teaches an apparatus operable in a mode in which the patient is provided stimulation independent of their choice and then requested to indicate, on the display using the stylus, where they feel the stimulation (Col. 14 @ 5-25). The selectable array of input zones are the possible positions on the display where the patient feels pain.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12, 13, 17, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann as applied to claims 1 and 11 above, and further in view of Brannon (US Pat. 6,193,678, hereafter referred to as Brannon).

Regarding **claim 12**, Mann does not teach a support member comprising a garment to be worn by the user. Brannon, however, teaches a stimulation system which includes a vest 12 containing a plurality of vibratory units 18 (Figure 2 and Col. 3 @ 55-67). It would have been obvious to one of ordinary skill at the time the invention was made to include the vest and vibratory units of Brannon in place of the implantable stimulation device in the system of Mann in order to provide a temporary stimulatory device that could be removed with relatively little effort.

Regarding **claim 13**, neither Mann nor Brannon teach a garment comprising a corset. However, given the vest described in claim 12 above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a corset in place of the vest in order to provide a temporary device that could be removed with relatively little effort as the garments provide the same structural purpose.

Regarding **claim 17**, Mann does not teach stimulator elements that comprise vibrator devices. Brannon, however, teaches vibratory units 18 (as shown in Figure 2and Col. 3 @ 55-67) that act as stimulator elements. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the vibratory units of Brannon in place of the implantable stimulation device in the system of Mann in order to provide a vibratory stimulus instead of an electrical stimulus.

Regarding **claim 23**, Mann teaches substantially all of the steps in the method of stimulation including:

- stimulating the surface of the body with an array of stimulator elements (electrode array 23), the array being operated to activate an activation zone configuration from a plurality of potential activation zone configurations (electrode groups 45), wherein the user interfaces with an interface device (programming system 10 including display screen 16, directional control device 12 and keyboard 14) such that interface zones of the interface device correlate to the active activation zone configuration of the array of stimulator element (Col. 15 @ 10-40).

Mann does not teach the stimulating of the surface of the body, but rather teaches stimulating through an implantable medical device comprising electrode array 23. Brannon, however,

teaches the stimulation of the surface of the body with an array of vibration units 18 (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the method step of stimulating the surface of the human body of Brannon in place of the stimulating of an implantable electrode array of Mann in order to provide a way to stimulate portions of the body temporarily using a device that could be removed with relatively little effort.

Regarding **claim 24**, Mann additionally teaches an interface device (programming system 10) that includes an array of interface zones (the zones shown in the pain drawing of Figure 12 shown on display 16) corresponding spatially to stimulator element activation zones (electrode groups 45 of Figure 5B).

Regarding **claim 25**, Mann additionally teaches a user input (using joystick 12 or keyboard 14) to a spatial input zone array of the interface device (the zones shown in the pain drawing of Figure 12 shown on display 16) that effect a corresponding spatial activation of the stimulator array (electrode groups 45 of Figure 5B).

Claims 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sieracki as applied to claim 1 above, and further in view of Brannon.

Regarding **claim 23**, Sieracki teaches substantially all of the method of stimulation including:

- stimulating the surface of the body with an array of stimulator elements (array of electrodes 33), the array being operated to activate an activation zone configuration from a plurality of potential activation zone configurations,

- wherein the user interfaces with an interface device (patient interactive system 24, including display 30 and stylus 31) such that interface zones of the interface device correlate to the active activation zone configuration of the array of stimulator element (Col. 8 @ 15-40 and Col. 9 @ 30-50).

Sieracki does not teach the stimulating of the surface of the body, but rather teaches stimulating through an implantable medical device comprising electrode array 23. Brannon, however, teaches the stimulation of the surface of the body with an array of vibration units 18 (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the method step of stimulating the surface of the human body of Brannon in place of the stimulating of an implantable electrode array of Sieracki in order to provide a way to stimulate portions of the body temporarily using a device that could be removed with relatively little effort.

Regarding **claim 26**, Sieracki additionally teaches an activation zone of the stimulator element array that provides stimulation independent of the user's choice and then requested to indicate, on the display using the stylus, where the stimulation is felt (Col. 14 @ 20-25).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Thursday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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6/13/2007

J. ALLEN SHRIVER
PRIMARY EXAMINER